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October 14, 2024
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Dogwood Therapeutics, Inc.

(DWTX-NASDAQ)

DWTX: Virios Therapeutics Becomes Dogwood Therapeutics; Focus on Chemotherapy-Induced Neuropathic Pain…

Based on our probability adjusted DCF model that takes into account potential future revenues of Halneuron, IMC-1, and IMC-2, DWTX is valued at $11.50/share. This model is highly dependent upon continued clinical success of its development products and will be adjusted accordingly based on future clinical results.

Current Price (10/14/24)	$4.12
Valuation	**$11.50**

OUTLOOK

On October 7, 2024, Virios Therapeutics, Inc. (VIRI) announced a business combination with privately-held Wex Pharmaceuticals, Inc. to form Dogwood Therapeutics, Inc. (DWTX). The name and ticker change, along with a 1:25 reverse split, took effect October 9, 2024. The new company will be focused on the advancement of three assets: Halneuron®, which is currently in a Phase 2b trial for the treatment of chemotherapy-induced neuropathic pain (CINP); IMC-1, which is a Phase 3-ready asset for the treatment of fibromyalgia; and IMC-2, which is currently in development to treat Long COVID. In connection with the combination, the company announced a $19.5 million debt financing that will be disbursed in two tranches: $16.5 million at closing and an additional $3 million in the first quarter of 2025. The financing is expected to fund operations through the end of 2025, with interim Phase 2b data for Halneuron expected in the second half of 2025.

SUMMARY DATA

52-Week High	**$21.00**
52-Week Low	**$2.83**
One-Year Return (%)	**-79.27**
Beta	**1.58**
Average Daily Volume (sh)	**178,272**
Shares Outstanding (mil)	**1**
Market Capitalization ($mil)	**$5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**12**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 A	0 E	0 E	0 E
2025					0 E
2026					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$2.07 A	-$1.96 A	-$1.62 A	-$1.43 A	-$7.05 A
2024	-$1.68 A	-$1.15 A	-$1.40 E	-$1.49 E	-$5.71 E
2025					-$4.57 E
2026					-$1.90 E

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Business Update

Virios Combines with Wex Pharmaceuticals to Form Dogwood Therapeutics

On October 7, 2024, Virios Therapeutics, Inc. (VIRI) announced a business combination with privately-held Wex Pharmaceuticals, Inc. to form Dogwood Therapeutics, Inc. (DWTX). The combined company will be focused on the clinical development of three assets: Halneuron®, which is currently in a Phase 2b clinical trial for the treatment of chemotherapy-induced neuropathic pain (CINP); IMC-1, a Phase 3-ready asset for the treatment of fibromyalgia; and IMC-2, which is currently in a Phase 2 trial for the treatment of Long COVID.

On October 9, 2024, the company's name changed from "Virios Therapeutics, Inc." to "Dogwood Therapeutics, Inc.", a 1:25 reverse split occurred, and the stock began trading on the Nasdaq under the ticker DWTX. Dogwood will be led by Chief Executive Officer Greg Duncan; Chief Medical Officer Mike Gendreau; Senior Vice President Operations Ralph Grosswald; Chief Financial Officer Angela Walsh; and Vice President Manufacturing Meng Zhou.

Halneuron®

The lead asset for Dogwood is Halneuron (tetrodotoxin, TTX), a sodium channel blocker currently in a Phase 2b clinical trial for the treatment of CINP. TTX was originally discovered in the pufferfish and subsequent research has identified the toxin in 13 phyla (in both *Eukarya* and *Bacteria*) that includes both marine and terrestrial eukaryotes (Lago *et al*., 2015). As a natural poison, TTX is extremely effective and is the most potent non-peptide neurotoxin known. It blocks the influx of sodium through voltage-gated sodium channels (Na_Vs), thereby preventing the initiation and propagation of action potentials in almost all neurons and muscle cells (Stevens *et al*., 2011).

Mammals possess nine voltage-gated sodium channels, $Na_V1.1$-$Na_V1.9$. TTX binds to $Na_V1.1$, $Na_V1.2$, $Na_V1.3$, $Na_V1.4$, $Na_V1.6$, and $Na_V1.7$ (Nieto *et al*., 2012). $Na_V1.7$ is expressed in all types of dorsal root ganglion (DRG) neurons, sympathetic neurons, Schwann cells, and neuroendocrine cells (Catterall *et al*., 2005). It is responsible for the perception of pain, which is supported by multiple lines of evidence. Individuals with loss-of-function mutations in the *SCN9A* gene (which encodes the alpha-subunit of $Na_V1.7$) experience a complete inability to sense pain (Cox *et al*., 2006) while those with a gain-of-function mutation in *SCN9A* experience erythromelalgia (Dib-Hajj *et al*., 2005). In animal models, $Na_V1.7$ nociceptor-specific knockout mice showed increased mechanical and thermal pain thresholds (Nassar *et al*., 2004). These results led researchers to hypothesize that TTX could be a potential therapeutic to control pain.

Halneuron Clinical Trials

The latest clinical trials investigating Halneuron include a Phase 2 cancer related pain (CRP) study and a Phase 2 CINP trial.

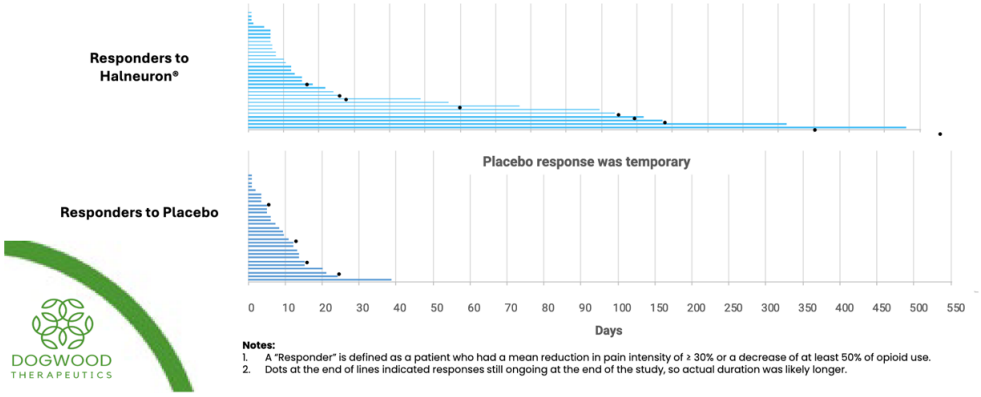
Phase 2 CRP Trial
This was a randomized, double blind, parallel design, multicenter trial that enrolled 165 patients with moderate to severe inadequately controlled CRP. All patients were on standard of care pain management. Halneuron or placebo was administered twice a day for four days and all patients recorded their pain response from days 5-8 (early post-injection period) and from days 9-15 (late post-injection period). The results showed a statistically significant improvement in pain outcomes for Halneuron, with 51% of Halneuron patients experiencing a ≥30% reduction in pain compared to only 35% in the placebo group, as shown in the following image.

Pain Outcome – Co-Primary Endpoint (Pain Intensity Difference and/or Opioid Use)

	TTX [1]		Placebo [2]		Difference
Responder [3]	33	51%	29	35%	16%
Non-Responder	32	49%	55	65%	
Total	**65**		**84**		
p-value	**0.046**				

Source: Dogwood Therapeutics, Inc.

For Global Impression of Pain Change, 55% of Halneuron patients reported an improvement in pain compared to 24% of placebo patients. Conversely, 70% of placebo patients reported no change or worse pain compared to only 37% of patients. In addition to a positive pain response, the duration of pain relief was much higher for Halneuron patients, as shown in the following figure. The average pain response for Halneuron responders was 57.7 days compared to 10.5 days for placebo responders. Lastly, over one-quarter of Halneuron responders (27%) had pain relief that lasted for 30 days or longer after one cycle of treatment.



Source: Dogwood Therapeutics, Inc.

Phase 2 CINP Trial

This was a randomized, double blind, dose-finding, placebo controlled, multicenter study in patients with CINP. Various doses of Halneuron were tested over four days of treatment followed by measurement over four weeks. The study included a total of 125 patients across five dosing cohorts (four active and one placebo). The results showed that a dose of 30 μg twice per day for four days demonstrated the highest level of pain reduction compared to placebo, with the responder analysis results given below.

Responder Analyses: 30% reduction in average NPRS[1] score from baseline to any 10 consecutive days

	TTX [2]	Placebo [3]
Yes	15 (58%)	8 (32%)
No	11 (42%)	17 (68%)
P-Value	**0.027**	
Odds Ratio (vs Placebo)	3.9	
95% CI for Odds Ratio	(1.08, 14.09)	

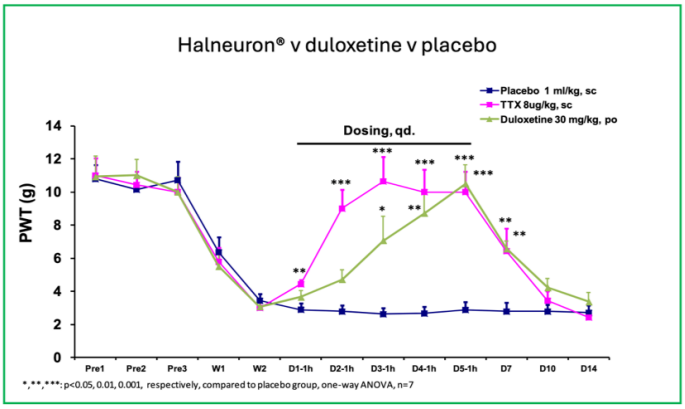
Source: Dogwood Therapeutics, Inc.

Halneuron is currently being evaluated in a Phase 2b clinical trial for CINP. We anticipate an update from the company on the trial in the first half of 2025 an interim data readout in the second half of 2025.

Background on CINP

CINP is the result of injury to the somatosensory nervous system following chemotherapy treatment (Colvin, 2019). For agents such as paclitaxel and oxaliplatin, the rate of CINP is up to 81% and 98%, respectively (Hershman *et al*., 2010; Gebremedhn *et al*., 2018). CINP begins as an acute pain syndrome that coincides with drug administration, however it can progress to a chronic condition following multiple rounds of therapy.

The only drug endorsed to treat CINP by the American Society of Clinical Oncology (ASCO) is duloxetine, which showed a significant reduction in pain in a Phase 3 clinical trial (Lavoie Smith *et al*., 2013). However, the drug is not FDA approved for the treatment of CINP. In addition, in a preclinical oxaliplatin-induced neuropathic pain model, Halneuron was superior to duloxetine based on the paw withdrawal threshold (PWT), a measure of pain tolerance.



- Halneuron®, at 8 µg/kg, sc, significantly increased the PWT in rats with oxaliplatin-induced neuropathy
- Duloxetine (positive control) at 30 mg/kg, q.d., increased the PWT in rats with oxaliplatin-induced neuropathy, but to a lesser degree compared to Halneuron®
- The effects of both compounds lasted approximately a week following cessation of dosing

Source: Dogwood Therapeutics, Inc.

Financial Update

As part of the business combination, Dogwood raised $19.5 million in a committed debt financing in two tranches: $16.5 million was funded at closing and an additional $3 million will be funded in the first quarter of 2025. This is expected to increase the company's cash runway through the end of 2025, which includes the expected interim results from the Halneuron Phase 2b CINP trial in the second half of 2025.

Following the business combination with Wex Pharmaceuticals, we have incorporated Halneuron into our DCF model. We model for a Phase 3 trial of Halneuron in CINP to initiate in 2026, an NDA filing in 2029, approval in 2030, and first sales in 2031. At this point, we estimate that a commercialization partnership will be entered into prior to commercial launch and that Dogwood will receive a 13% royalty on net sales. In the U.S., we estimate for peak sales seven years following launch of approximately $1.2 billion. In the E.U., we estimate for commercial sales to begin in 2032 and peak sales seven years following launch of approximately $500 million. Using a 12% discount rate and a 50% probability of approval leads to an NPV for Halneuron of $171 million. When combined with the NPV's for IMC-1 and IMC-2 along with the estimated current cash level leads to an NPV for Dogwood of $272 million.

As part of the business combination, Dogwood effected a reverse stock split of 25-for-1. In addition, Sealbond, the sole shareholder of Wex Pharmaceuticals and an indirect wholly-owned subsidiary of CK Life Sciences Int'l Inc., received 211,383 shares of common stock and 2,108.3854 shares of convertible preferred stock with a conversion ratio of preferred to common of 1:10,000. The convertible preferred stock will not be converted to common shares without shareholder approval in compliance with the rules of the Nasdaq Stock Market. In addition, Virios shareholders will receive a nontransferable contingent value right (CVR) to receive certain

proceeds received by Dogwood, if any, related to future upfront, development, or regulatory milestone payments resulting from corporate partnership transactions of IMC-1 and IMC-2.

We estimate the company's fully diluted share count is approximately 23.6 million shares. Dividing the calculated NPV by the estimated fully diluted share count leads to a valuation of $11.50.

Conclusion

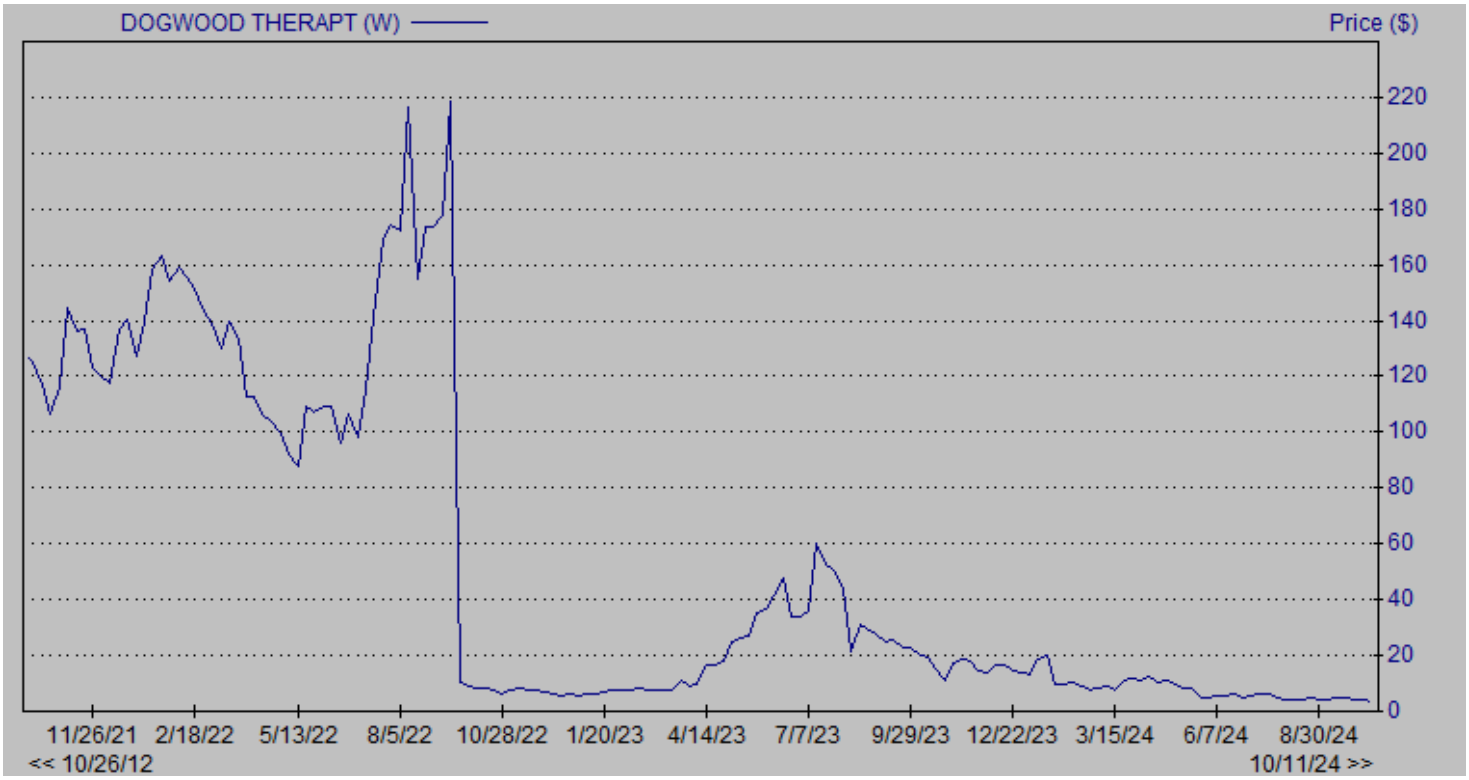
We view the combination of Virios and Wex as a logical step for each company as Dogwood Therapeutics now has an additional, complementary development asset in Halneuron to go alongside IMC-1 and IMC-2. In the near-term, we anticipate results from the ongoing Phase 2 study of IMC-2 in Long Covid in the fourth quarter of 2024. These results will dictate how the company proceeds in its development, whether to pursue a development partnership or advance it further on its own. For Halneuron, we anticipate interim results from the Phase 2b study in CINP in the second half of 2025. Lastly, for IMC-1 we expect Dogwood will continue to pursue a partnership for its advancement in fibromyalgia.

PROJECTED FINANCIALS

Dogwood Therapeutics, Inc.	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
Halneuron	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
IMC-2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$1.7	$0.3	$0.3	$0.7	$0.8	$2.2	$3.0	$4.0
SG&A	$3.7	$1.0	$0.7	$0.9	$0.9	$3.5	$3.5	$3.7
Operating Income	($5.4)	($1.3)	($1.1)	($1.6)	($1.7)	($5.7)	($6.5)	($7.7)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($5.3)	($1.3)	($1.0)	($1.6)	($1.7)	($5.6)	($6.4)	($7.6)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.3)	($1.3)	($1.0)	($1.6)	($1.7)	($5.6)	($6.4)	($7.6)
Reported EPS	**($7.05)**	**($1.68)**	**($1.15)**	**($1.40)**	**($1.49)**	**($5.71)**	**($4.57)**	**($1.90)**
Weighted Shares Outstanding	0.8	0.8	0.9	1.1	1.1	1.0	1.4	4.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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